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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,327	09/27/2006	Ryoji Noyori	129542	3317

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EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
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1621

NOTIFICATION DATE	DELIVERY MODE
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03/15/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

OfficeAction25944@oliff.com
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Office Action Summary	Application No.	Applicant(s)	
	10/594,327	NOYORI ET AL.	
	Examiner	Art Unit	
	Rosalynd Keys	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) 12, 14-16, 18, 19, 21, 22, 24, 25, 27, 28, 30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 13, 17, 23, 26, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

1. Claims 1-10 and 20 have been cancelled.

Claims 11-19 and 21-31 are pending in this application.

Claims 12, 14-16, 18-19, 21, 22, 24, 25, 27, 28, 30 and 31 are withdrawn from consideration as non-elected subject matter.

Claims 11, 13, 17, 23, 26, and 29 are rejected.

Election/Restrictions

2. Claims 12, 14-16, 18-19, 21, 22, 24, 25, 27, 28, 30 and 31 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 16, 2008.

Response to Arguments

3. Applicant's arguments filed November 12, 2009 have been fully considered but they are not persuasive.

The Applicants submit that there is no evidence that the specific process of Watanabe could be practiced without using a base or that an ordinarily skilled artisan would understand Watanabe to be teaching such in a general manner. Instead, the evidence is to the contrary.

The Examiner respectfully disagrees. Watanabe clearly teaches that the their reduction process can take place in the absence of a base (see col. 4, line 47 to col. 5, line 25; col. 5, lines 42-52; col. 20, lines 10-22; col. 22, lines 16-19; and claims 1 an 2).

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The Applicants submit that Watanabe, in examples 1-4, discloses a ruthenium chloride catalyst RuCl (Tsdpen)(p- cymene). Ohkuma II discloses that in order for this particular catalyst to perform asymmetric hydrogenation of ketone, it must be first converted into an amide complex by treatment with a strong base, which is then converted into a monohydride complex to form the active catalyst species.

This submission is not persuasive because a base may be required to form the ruthenium complex that is used as a catalyst to carry out the reduction process of Watanabe, but it is not required to carry out the reduction process, as the catalyst of Watanabe can be prepared prior to its use in the reduction reaction (see col. 20, lines 10-34).

The Applicants submit that examples 1-4 of Watanabe disclose the use of a base in the asymmetric reduction step.

This submission is not persuasive because a prior art disclosure is not limited to its working examples or to its preferred embodiments, but must be evaluated for what it teaches those of ordinary skill in the art. Merck & Co. Inc. v. Biocraft Labs. Inc., 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989); In re Fracalossi, 681 F.2d 792, 794 n.1, 215 USPQ 569, 570 n.1 (CCPA 1982); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976); In re Boe, 355 F. 2d 961, 965, 148 USPQ 507, 510 (CCPA 1966). In the instant case, Watanabe clearly teaches that the their asymmetric reduction process can take place in the absence of a base (see col. 4, line 47 to col. 5, line 25; col. 5, lines 42-52; col. 20, lines 10-22; col. 22, lines 16-19; and claims 1 an 2).

The Applicants submit that there exists no reason or rationale for one of ordinary skill in the art to modify Watanabe to use the hydrogen gas disclosed by Ikariya because the active catalyst species derived from the ruthenium chloride catalyst of Watanabe was not known to activate hydrogen gas as a hydrogen source to hydrogenate ketones; and that in fact, it was

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thought in the prior art that hydrogenating ketones using hydrogen gas as a hydrogen source was impossible regardless of the presence or absence of a base. See Fujii at page 2522, right column, lines 22-24 (describing that hydrogen gas contributes little to the generation of alcohol, and that a reaction using hydrogen gas/acidic acid gives a poor yield of 5% and an asymmetrical yield of 75% ee).

This submission is not persuasive because Ikariya et al. teach that it is known in the art that asymmetric hydrogenation of ketones could be accomplished using a ruthenium catalyst, including ruthenium chloride catalysts, with pressurized hydrogen or a hydrogen donor in the absence of a base. (See entire computer generated English translation, in particular paragraphs 0015 and 0040-0043). This teaching is even corroborated by the Fujii reference supplied by the Applicants (see the first paragraph of column 1 on page 2521, wherein it is disclosed that catalytic transfer hydrogenation of ketones to alcohols with 2-propanol (a hydrogen donor) sometimes offers an attractive alternative to the reaction with molecular hydrogen because of the favorable properties of the organic hydrogen source). In fact, Fujii even provides further motivation to utilize molecular hydrogen instead of 2-propanol as the reverse process may occur due to the structural similarity of the hydrogen donor and the product. Thus, one having ordinary skill in the art at the time the invention was made would have known that hydrogen gas and hydrogen donors are both suitable for use in the hydrogenation of ketones to the corresponding alcohols. Thus, there would have been a reasonable expectation of success when substituting the hydrogen donors of Watanabe with pressurized hydrogen as taught by Ikariya. Further, there would have been motivation to do so in order to avoid a reverse process. With respect to the results obtained in Fujii at page 2522 this is the result obtained when hydrogen gas is used in a 2:1 mixture of acetic and triethylamine. However, Fujii taught that asymmetric reduction can be achieved with a 5:2 formic acid-triethylamine azeotropic mixture

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(see Fujii at paragraph 2 of col. 1 on page 2521 and page 2522, right column, lines 29-35).

Thus, contrary to the submission by Applicants Fujii does not teach that it is impossible to hydrogenate ketones using hydrogen gas as a hydrogen source.

For the above reasons, as well as those of the previous office action, mailed August 21, 2009, the instant claims are obvious over the combination of Watanabe and Ikariya. Therefore, the rejection of Claims 11, 13, 17, 23, 26, and 29 under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al (US 6,686,505 B2)) in view of Ikariya et al. (JP 11-189600) is maintained.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 11, 13, 17, 23, 26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al (US 6,686,505 B2)) in view of Ikariya et al. (JP 11-189600), for the reasons given in the previous office action, mailed August 21, 2009.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is (571)272-0639. The examiner can normally be reached on M-F 5:30 am-7:30 am and 9:15 am-3:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rosalynd Keys/
Primary Examiner, Art Unit 1621

March 10, 2010